PHILIPS

K961374

Philips Medical Systems

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AUG 19 1996

Department of Health and Human Services
Center for Devices and Radiological Health
Office of Device Evaluation
Pre-Market Notification section

. Qual. Ass. Dpt. XSB/XCB
XB030-960317/RR/gd

1996.03.01

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

for

PHILIPS MULTI DIAGNOST 4, UNIVERSAL TILT C-ARM SYSTEM

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

The undersigned certifies that the 510(k) Pre-Market notification for the above referenced product contains adequate information and data to enable CDRH to determine substantial equivalence.

This information and data is summarized as follows:

1. The Multi Diagnost 4 system subject to Federal Performance Standards, defined in 21CFR - part 1000;

2. The Multi Diagnost 4 system will be manufactured in accordance with voluntary safety standards, such as UL 187;

3. The information for Users contains comprehensive information to insure safe and effective use;

4. Past experience with substantially equivalent predicate devices has shown our device to be safe and effective when used as directed in the Information for Users.

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